

CLAIMS

We claim:

1. A method of detecting cancer in a patient, comprising:
 - a) providing a urine sample from a patient; and
 - b) analyzing said urine sample for a nucleic acid sequence or nucleotide modification indicative of cancer, that has crossed the kidney barrier.
2. The method of claim 1, wherein said step of analyzing for said nucleic acid sequence is selected from the group consisting of hybridization, cycling probe reaction, polymerase chain reaction, nested polymerase chain reaction, polymerase chain reaction - single strand conformation polymorphism, ligase chain reaction, strand displacement amplification and restriction fragments length polymorphism.
3. The method of claim 1, wherein analyzing for said nucleic acid sequence comprises amplifying said nucleic acid sequence.
4. The method of claim 1, wherein said analyzing comprises quantifying said nucleic acid sequence.
5. The method of claim 1, wherein said nucleic acid sequence contains an anomaly indicative of colon cancer.
6. The method of claim 1, wherein said nucleic acid sequence contains a K-ras mutation.
7. The method of claim 1, further comprising, reducing DNA degradation in said urine sample.
8. The method of claim 7, wherein reducing DNA degradation comprises treatment with a compound selected from the group consisting of: ethylenediaminetetraacetic acid, guanidine-HCl, Guanidine isothiocyanate, N-lauroylsarcosine, and Na-dodecylsulphate.

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9. The method of claim 1, wherein said urine sample has been held in the bladder less than 12 hours.

10. The method of claim 1, wherein step (b) comprises substantially isolating said nucleic acid sequence.

11. The method of claim 10, wherein said nucleic acid sequence is substantially isolated by precipitation.

12. The method of claim 10, wherein said nucleic acid sequence is substantially isolated by treatment with a solid adsorbent material.

13. The method of claim 1, further comprising, filtering said urine sample to remove contaminants.

14. The method of claim 1, wherein said nucleotide modification is selected from the group consisting of: a deletion, an addition, an addition-deletion, a substitution, an insertion, a reversion, a transversion, a point mutation, a microsatellite modification, methylation or a nucleotide adduct formation.

15. A method of monitoring transplanted material in a patient, comprising:

a) providing a urine sample suspected of containing nucleic acid from transplanted material; and

b) analyzing said urine sample for a nucleic acid sequence that has crossed the kidney barrier and that was not present in the patient prior to

transplantation.

16. The method of claim 15, wherein said nucleic acid sequence is not present in cells of the urinary tract of said patient.

17. The method of claim 15, wherein said analyzing comprises amplifying said nucleic acid sequence with a primer substantially complementary to a part of said nucleic acid sequence that does not occur in cells of the urinary tract of the patient, to make amplified target DNA, and detecting the presence of said amplified target DNA.

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18. The method of claim 17, wherein amplifying comprises performing a
polymerase chain reaction.
19. The method of claim 18, further comprising step (a)(i) reducing DNA
degradation in said urine sample.
20. The method of claim 19, wherein reducing DNA degradation is by treatment
with a compound selected from the group consisting of:
ethylenediaminetetraacetic acid, guanidine-HCl, Guanidine isothiocyanate, N-
lauroylsarcosine, and Na-dodecylsulphate.
21. The method of claim 18, wherein said urine sample has been held in the
bladder less than 12 hours.
22. The method of claim 18, further comprising step (a)(i) substantially isolating
said nucleic acid sequence.
23. The method of claim 22, wherein said nucleic acid sequence is substantially
isolated by precipitation.
24. The method of claim 22, wherein said nucleic acid sequence is substantially
isolated by adsorption on a resin.
25. The method of claim 18, further comprising step (a)(1) filtering said urine
sample to remove contaminants.
26. The method of claim 25, wherein said filtering removes DNA comprising
more than about 1000 nucleotides.

27. A method of monitoring cancer treatment in a patient, comprising:
a) providing a urine sample from a patient; and
b) analyzing said urine sample to quantify a nucleic acid sequence indicative
of cancer, that has crossed the kidney barrier.

28. A diagnostic kit for detecting a genetic mutation indicative of cancer in the
DNA of a patient, comprising: reagents to facilitate the isolation of DNA
from urine; reagents to facilitate amplification of DNA by the polymerase
chain reaction; a heat stable DNA polymerase; and an oligodeoxynucleotide

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specific for a sequence only occurring in a genetic mutation characteristic of cancer.

29. A diagnostic kit for detecting DNA from a transplanted material in the urine of a patient, comprising: reagents to facilitate the isolation of DNA from urine; reagents to facilitate amplification of DNA by the polymerase chain reaction; a heat stable DNA polymerase; and an oligodeoxynucleotide specific for a sequence that occurs in the transplanted material, and did not occur in the patient prior to transplantation.

30. A method of analyzing a target nucleic acid sequence in urine, comprising:

- a) providing a urine sample; and
- b) assaying said urine sample for a target DNA fragment that has crossed the kidney barrier.

31. The method of claim 30, wherein said target DNA fragment has a modification characteristic of a disease.

32. The method of claim 31, wherein said modification is selected from the group consisting of: a deletion, an addition, an addition-deletion, a substitution, an insertion, a reversion, a transversion, a point mutation, a microsatellite modification, methylation or a nucleotide adduct formation.

33. The method of claim 30, further comprising c) analyzing said target DNA fragment for a modification characteristic of a disease.

34. The method of claim 33, wherein said disease is cancer.

35. The method of claim 33, wherein said disease is related to aging.

36. The method of claim 30, further comprising, step (a)(i) reducing DNA degradation in said urine sample.

37. The method of claim 35, wherein reducing DNA degradation comprises treatment with a compound selected from the group consisting of: ethylenediaminetetraacetic acid, guanidine-HCl, Guanidine isothiocyanate, N-lauroylsarcosine, and Na-dodecylsulphate.

38. The method of claim 30, wherein said urine sample has been held in the bladder less than 12 hours.

39. The method of claim 30, wherein step (b) comprises substantially isolating said target DNA fragment that has crossed the kidney barrier.

5 40. The method of claim 39, wherein said target DNA fragment that has crossed the kidney barrier is substantially isolated by precipitation.

41. The method of claim 39, wherein said target DNA fragment that has crossed the kidney barrier is substantially isolated by treatment with a solid adsorbent material.

10 42. The method of claim 30, further comprising, step (a)(i) filtering said urine sample to remove contaminating nucleic acids.

43. The method of claim 42, wherein said filtering removes DNA comprising more than about 1000 nucleotides.

15 44. The method of claim 30, wherein said target DNA fragment methylation characteristic of a disease.